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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 10/594,526 | 11/27/2006 | Christophe D'Hulst | 0512-1352 | 9478 |
| 466 | 7590 | 11/12/2009 | EXAMINER | |
| YOUNG & THOMPSON | | | PAGE, BRENT T | |
| 209 Madison Street | | | ART UNIT | PAPER NUMBER |
| Suite 500 | | | | |
| Alexandria, VA 22314 | | | 1638 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/12/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/594,526 | D'HULST ET AL. |
| | Examiner | Art Unit |
| | BRENT PAGE | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-13 and 19-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-13 and 19-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

The reply filed on 07/22/2009 is hereby acknowledged. The cancellation without prejudice of claims 14-18 is hereby acknowledged. The addition of new claims 19-30 is hereby acknowledged. Claims 10-13 and 19-30 are pending and examined herein on the merits.

Claim Rejections - 35 USC § 112-scope of enablement

Claims 10-13 remain rejected and claims 19-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for random insertional mutagenesis and the screening of a phenotype wherein the enzymatic action of starch phosphorylase appears to be reduced or abolished, does not reasonably provide enablement for the insertion of any number of nucleotides at any point along any length of any gene other than the starch phosphorylase gene wherein starch phosphorylase is switched off in which starch grain size and/or starch content of any plant part is increased as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are rejected for the reasons of record in the office action mailed out on 01/22/2009 as well as the reasons presented below.

Applicant's arguments filed 07/22/2009 have been fully considered but they are not persuasive.

Applicants urge that the claim amendments obviate the rejection of record by specifying that the gene coding for starch phosphorylase is switched off by introducing a mutation in the genome of a plant (see pages 6-7 of response).

This is not persuasive because the claim amendments do not specify that that mutation is introduced into the starch phosphorylase gene. Proteins that interact with starch phosphorylase may potentially affect the function of the gene, but no such genes are discussed in the specification, and no guidance is given for any mutations in any such genes wherein starch phosphorylase would be switched off.

Applicants urge that the insertion of a piece of T-DNA on the order of 5 to 25 kb in length would clearly produce a dramatic disruption of gene function (see page 7 of response).

This is not persuasive because none of the claims as currently written actually require the insertion of a piece of T-DNA in the starch phosphorylase gene. The claims are either drawn to T-DNA inserted anywhere in the genome, wherein starch phosphorylase is switched off, or any number of nucleotides as small as 2bp inserted into the starch phosphorylase gene. It is suggested that a recitation of a T-DNA insertion into the starch phosphorylase gene would overcome this portion of the scope of enablement rejection.

Applicants urge that any technique enabling the disruption of the gene coding for starch phosphorylase is suitable to achieve the present invention (see page 8 of response).

This is not persuasive, because the specification only gives guidance for T-DNA insertion leading to the level of gene suppression required for the claimed phenotype. As discussed in the previous office action, other methods may lead to reduced levels of starch phosphorylase but still not lead to the claimed phenotypes due to inefficient gene silencing.

Claim Rejections - 35 USC § 112-2nd paragraph

Applicant's arguments, see pages 8-9, filed 07/22/2009, with respect to omitting essential method steps have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claims 10 and 13 has been withdrawn.

Claim Rejections - 35 USC § 102

Applicant's arguments, see pages 9-10, filed 07/22/2009, with respect to anticipation have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claims 10, 11 and 13 has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 10-13 remain rejected and claims 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Critchley et al (2001 The Plant Journal 26:89-100) and in view of Kossman et al (US patent 6686514). The claims are rejected for the

reasons of record in the office action mailed out on 01/22/2009 as well as the reasons presented below.

Applicant's arguments filed 07/22/2009 have been fully considered but they are not persuasive.

Applicants urge that Critchley et al teaches away from the instantly claimed invention and one would not have been motivated to inactivate starch phosphorylase to increase the starch content and the size of starch grains (see pages 11-12 of response).

This is not persuasive because Applicants are arguing the references individually instead of taking them as a whole. Critchley et al is cited primarily to establish that inactivation of genes via T-DNA insertion was well known in the art and further has even been used to increase starch content. The reference to starch phosphorylase was only to demonstrate that the gene was known to play a role in starch content and size. Kossman et al was cited to show that starch phosphorylase had previously been switched off in the prior art. One would have been motivated by the results from Kossman et al in light of the methods by Critchley et al and the known role that starch phosphorylase plays in starch content to switch off starch phosphorylation by way of T-DNA insertion as taught by Critchley et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants urge that both Smith et al and Sonnewald et al teach away from the present invention based on their statements and observations about the affect of suppressing starch phosphorylase in the leaves of plants (see pages 12-14 of response).

This is not persuasive because the prior art teaches the switching off of starch phosphorylase meeting the limitation of the present claims. The breadth of the claims indicate that any mutation reducing the activity of starch phosphorylase would result in the phenotype of the currently written claims. Because the prior art teaches such a reduction in starch phosphorylase, the phenotype if enabled generally, naturally follows. However, if Applicants have achieved a surprising result that contradicts the prior art, such a result would only apply to the demonstrated mutation of starch phosphorylase and not the entire broad scope currently claimed.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638